

510(k) Summary

OCT 23 2009

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4. **Date Summary Prepared :** March 27, 2009
5. **Device Name :** KneeKG
6. **Predicate Devices :** Code CX1 Motion Analysis System (K033514)
InstaTrak with Multiple dataset Navigation (K040050)
7. **Device Description :**

The KneeKG measures and analyzes the 3D position and movement of electromagnetic markers placed on the knee of patients whose movement function is to be assessed. The movement data are acquired into a host PC which then analyses and displays the data on graphs and printed reports.
8. **Intended Used :**

General application for the measurement and recording of 3D position and movement.
9. **Indication for Use:**

Measure and analyze 3D position and movement by placing markers on the limbs of patients whose movement function is to be assessed.
10. **Target Population:**

Appropriate for assessing the 3D motion of the knee of patients who have impaired movement functions off an orthopaedic cause. Not intended for children (i.e. patients must be 18 old or older.
11. **Technological characteristics in comparison with predicate device :**

The KneeKG is substantially equivalent to the Coda CX1 Motion analysis system (K033514) manufactured by Charnwood Dynamics Ltd as a means of measuring the three-dimensional movements of subjects, including such activities as walking. Both systems acquire the movement data into a host PC, which then analyzes and displays motion data onscreen or in printed reports. The predicate Coda CX1 Motion analysis system (K033514) is using an optical method and

the KneeKG is using an electromagnetic position system. For this characteristic, the KneeKG is compared with the second predicate, the InstaTrak with Multiple dataset Navigation (K040050) manufactured by GE Medical Systems Navigation and Visualization, which is using the same technology.

- 12. Conclusion Drawn:** Substantially equivalent to the cited predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 26 2009

Émovi Inc.
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Mr. Emmanuel Montini
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Montreal, Quebec
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Re: K091000
Trade/Device Name: KneeKG
Regulatory Class: Unclassified
Product Code: LXJ
Dated: October 20, 2009
Received: October 22, 2009

Dear Mr. Montini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

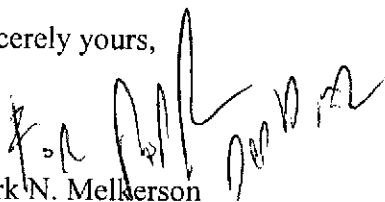
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkersen
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): -----

Device Name: KneeKG

Indications For Use:

Measure and analyze 3D position and movement by placing markers on the knees of patients whose movement function is to be assessed.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 FOR M. MELKERSEN
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091000